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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/738,912

12/16/2003

Herman E. Snyder

53285-US-CNT

8356

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7590

02/26/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

BOECKMANN, JASON J

ART UNIT

PAPER NUMBER

3752

MAIL DATE

DELIVERY MODE

02/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/738,912	Applicant(s) SNYDER ET AL.	
	Examiner Jason J. Boeckmann	Art Unit 3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 42 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that the specification indicates that the excipient has a glass transition temperature of above 35 degrees C, and is silent about the particles having a glass transition temperature. Therefore, there is no support for the particles having a glass transition temperature of above 35 degrees C.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 26, 27, 29-34, 36-41, 44-46 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Platz et al. (6,051,256).

Platz et al. shows a spray drying system for forming a pharmaceutical formulation, the system comprising: an atomizer (57), the atomizer comprising a first, annular channel (100) through which a pharmaceutical liquid flows, the channel comprising a constriction (104) for spreading the pharmaceutical liquid into a thin film in the channel, the atomizer further comprising a second channel (102) through which an atomizing gas flows, the second channel being positioned so that the atomizing gas impinges the liquid thin film to produce droplets; a drying chamber (50) to dry the droplets to form particles; and a collector (76) to collect the particles.

Regarding claims 27, 34 and 46; the constriction has a diameter of less than .02 inches (column 14, line 1).

Regarding claims 29, 36, and 46 the device has a third channel for gas flow (the drying air of figure 2).

Regarding claims 31, 32, 38, 39, 49 and 50, the inlet gas stream has temperature of above 90 degrees C and the outlet of above 50 degrees C (see claim 10).

Regarding claim 40, the pharmaceutical liquid includes an active ingredient (column 8, line 60) and an excipient (column 9, line 35).

Regarding claims 41 and 51, the particles have a rugosity above 2 (column 6, line 2).

Regarding claim 44, the particles have a diameter of less than 20 micro meters (column 6, line 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 35, 42, 43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (6,051,256).

Regarding claims 28, 35 and 47, Platz et al. shows all aspects of the applicant's invention as in the rejection of claims 17 and 22 above, but fails to disclose that the constriction has a diameter of less than .005 inches. However, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make the diameter of the constriction less than .005 inches since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Additionally, it is well known in the art that the smaller the constriction, the faster the fluid velocity will be going through the restriction, as well as the more turbulent it will

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be. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the constriction diameter less than .005, in order to increase the velocity and the turbulence of the fluid as it passes through the restriction point.

Regarding claims 42 and 43, Platz et al. shows all aspects of the applicant's invention as in the rejection of claim 33 above, but fails to specifically disclose that the particles have a density of less than $.5\text{g/cm}^3$, and that the glass transition temperature is above 35 Degrees C.

However, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a material that makes the particles have a density of less than $.5\text{g/cm}^3$, and with a glass transition temperature of above 35 degrees C, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use of the device.

Response to Arguments

Applicant's arguments with respect to claims 26-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason J. Boeckmann whose telephone number is (571)272-2708. The examiner can normally be reached on 8:00- 5:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Len Tran can be reached on (571) 272-1184. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. J. B./

Examiner, Art Unit 3752

2/18/2009

/Len Tran/

Supervisory Patent Examiner, Art Unit 3752